GUIDELINES FOR HUMAN SUBJECT RESEARCH

WITHIN THE INTELLIGENCE COMMUNITY

Attachment

1. The key procedural elements of the Department of Health, Education and Welfare (DHEW) Guidelines regarding Institutional Review Boards and Informed Consent Procedures are outlined below. The full text of the Guidelines may be found in the Code of Federal Regulations.

2. Institutional Review Board (IRB)[1] reviews research proposals and is comprised of non-vested interest personnel which will include lay as well as scientific members and when possible a representative from the population from which the subject population is to be drawn. No research procedures using human subjects will be undertaken until the IRB has reviewed and approved the research by determining that:

a. Subjects will not be at risk physically, psychologically, or socially; or, if the subjects will be at risk, that the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept or reject the risks. The definition of risk does not include the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.

b. The rights and welfare of any such subjects will be adequately protected including the right of confidentiality.

c. Informed consent will be obtained in writing *and witnessed by a disinterested third party.** —

d. The conduct of the research activity will be reviewed at timely intervals. Such review must occur no less than annually.

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[1]See Title 45, Code of Federal Regulations, Part 46, especially paragraphs 46.6 and 46.7.

*The italicized portion of this sentence is an additional condition imposed by Executive Order 11905.

3. Informed Consent Procedures[2] will exclude exculpatory language and include:

a. An explanation, in language understandable to the subject, of the procedures to be followed and their purpose, including the identification of any procedures which are experimental.

b. A description of any attendant discomforts or risks reasonably to be expected.

c. A description of any benefits reasonably to be expected.

d. A disclosure of alternative procedures that might be advantageous to the subject.

e. An offer to answer any inquiries concerning the procedures.

f. An instruction that the person is free to withdraw his or her consent and to discontinue participation in the research activity at any time without prejudice to the subject.

[2]Ibid., especially paragraphs 46.3 and 46.10.